

## **REMARKS**

### **THE PENDING CLAIMS**

Claims 108-109, 112-113, 115-130 and 132 were pending in this application and have been canceled, and claims 141-183 substituted therefor. Accordingly, claims 1-140 have been canceled, and claims 141-183 remain pending in this application. The applicant requests consideration and allowance of the present claims in view of the arguments presented at the interview of August 23, 2005, and the contents of the Belkin and Fedeli declarations submitted herewith.

### **THE INTERVIEW**

Examiner Fay is thanked for a most cordial and helpful interview granted the applicant's attorney on August 23, 2005. Prior to this date the applicant faxed to the examiner drafts of proposed new claims, an expert's declaration and clinical trial data relating to the claimed invention. During the course of the interview the applicant's attorney explained that the new claims were patentable over the previously cited prior art (the WO '91 publication), and the examiner concurred. In addition, the attorney discussed the expert declaration's establishing that a list of diseases and conditions being listed are different from "dry eye". Thereafter the discussion turned to a clinical comparison of patients treated with an agent of the invention and its comparison to a control treated with a hyaluronic acid salt. Two Declarations containing the information discussed during the interview are attached herewith.

Examiner Fey is further thanked for an informal interview/telephone conference hwd on November 30, 2005, during which the proposed claims and prior art were discussed. The examiner's suggestions have been incorporated into the texts of the presently submitted claims. The following remarks contain the arguments exchanged on both occasions, and an expansion thereof.

### **THE OBVIOUSNESS REJECTION**

Claims 108-109 and 116 stand rejected under 35USC1.103, allegedly as being unpatentable over WO 91/12808 (the WO 91 publication). This rejection is emphatically traversed.

The WO '91 publication is different from the claimed invention, and fails to describe or suggest all elements of the claimed method. As pointed out during the interview by the applicant's attorney, WO '91 is directed to a composition of phospholipids, not lipoproteins, as is the composition administered by the claimed method.

Nowhere does the WO '91 publication describe or suggest using lipoproteins, let alone for the treatment of an eye condition, as does the claimed invention. Moreover, the diseases being treated by the WO 91/12808 publication are medically different from that of the claimed method. This is clearly delineated in the Belkin Declaration submitted herewith. While the prior art relates to dry eye problems the claimed method for the treatment of disorders such as mechanical abrasion of the cornea; corneal epithelial defects created by spontaneous peeling of the epithelium; corneal damage following photo-refractive keratectomy; injuries caused by chemical damage to the corneal epithelium and conjunctiva; chronic edema of cornea with recurrent erosion of epithelium; and conditions following damage of epithelia due to radial keratotomy. These conditions and their treatment are unrelated to the treatment of dry eyes, whether by lubrication or by suppressing inflammation. None of the therapies employed to cure the corneal conditions listed above is associated with the treatment of dry eye.

Therefore, a person skilled in the art would not consider using a dry eye medication to treat disorders listed above, except occasionally for the temporary relief of some of their minor symptoms, for the treatment of the above conditions. The Fedeli Declaration addresses the effectiveness of the claimed treatment over standard treatments employed in the art.

In view thereof, the examiner is invited to withdraw this rejection.

#### **THE OBJECTED TO CLAIMS**

Claims 112-113, 115, 117-130 and 132 stand objected to, as being dependent on a rejected claim.

The indication by the examiner that claims 112-113, 115, 117-130 and 132 are solely objected to because they depend from a rejected claim, is acknowledged with thanks.

Although these claims have been canceled, their contents have been incorporated into the new set of claims, and should be allowable.

#### **THE AMENDMENT TO THE TITLE**

The title has been amended to better correspond to the text of the present claims.

#### **THE ADVISORY ACTION**

The examiner indicated in the Advisory Action and during the telephone conference held on November 30, 2005, that claim 142 was directed to a phospholipid, and that there was no antecedent basis in claim 141 for this product.

Claim 142 includes a phospholipids(s) as one of several components. This combination is neither disclosed nor obvious over the art cited against the claims. Moreover, claims 142 does not seem to be afflicted by a lack of antecedent basis in claim 141, phospholipids being a class of non-cholesterol lipid component present in claim 141. The applicant has rewritten the claim to clarify this matter.

#### **THE AMENDMENTS TO THE CLAIMS**

The applicant submits that the amendments to the claims are fully supported by the specification as filed, and by the original claims. The present amendments are believed to introduce no objectionable new matter into the claims. The present claims are believed to be definite, enabled, and fully supported by the written description in the specification as filed, and the original claims. For example, support for the texts of the pending claims may be found as indicated in the following table showing the claim number and some of the pages where support may be found.

<b>Support for Newly Added Claims 141-183</b>	
<b>Claims</b>	<b>Page, Lines (PCT specification)</b>
141	3, 18-22; 4, 9-23; 5, 16-17; 6, 1-3, 23-25; 8, 21-24
142	3, 21-22; 4, 11-12; 7, 28-29; 12, 10-20
143	6, 1-28 to 7, 1-19
144	4, 14-28; 5, 1-5; 8, 16-17
145	4, 18; 5, 4
146	2, 3; 4, 17-18
147	4, 19
148	4, 19; 2, 4-5
149	4, 22
150	4, 22
151	4, 17
152	4, 18; 2, 4
153	4, 17, 19
154	4, 20-21, 27; 5, 4, 7
155	4, 3-5
156	4, 6-10
157	4, 6-13
158	4, 8-22; 5, 10-11
159	4, 28; 5, 5
160	7, 20-21, 26-27
161	7, 26 to 8, 4; 8, 5-7
162	7, 26 to 8, 4; 8, 5-7
163	8, 9-10
164	8, 9
165	8, 10-11

166	8, 12
167	8, 12
168	8, 18-20
169	8, 23-24
170	8, 29
171	4, 15-22, 29; 5, 4; 2, 8
172	
173	4, 24-25
174	6, 3-8, 9-10, 18-28; 7, 1-19
175	6, 15-17
176	6, 17
177	6, 3-8
178	6, 18-20
179	6, 8
180	7, 7-19
181	4, 12-13, 26-28
182	9, 26-27; Examples II, 1 and 2 and III
183	7, 20-21, 29; 8, 1-4
184	7, 26 to 8, 4

#### **THE BELKIN AND FEDELI DECLARATIONS**

A declaration signed by Dr. Belkin, "the Belkin Declaration" is attached for the examiner's review and consideration. As discussed by the applicant's attorney during the interview, the Belkin Declaration establishes a clear difference between "dry eye" and the diseases and conditions treated by the claimed invention.

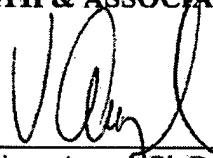
A second declaration, "the Fedeli Declaration", is also attached for the examiner's review and consideration. The Fedeli Declaration describes a pilot clinical trial corresponding to the claimed process. The Fedeli Declaration shows that the claimed method of treatment is superior to the conventional Hyaluronic Acid (HA) treatment. The results of this pilot study showed a definite trend towards better efficacy for the treatment with TBX-024, the claimed treatment, than for the treatment with HA. The claimed treatment performed better, although not yet statistically significantly better, in terms of accelerating the patient's recovery time and of reducing the severity of symptomatology. Further studies are in progress to demonstrate the clinical efficacy of TBX-024 in wound healing.

Now, these are unexpected results that clearly support the patentability of the claimed invention.

**CONCLUSIONS**

In view of the above amendments and remarks this application is believed to be in condition of allowance. Favorable action and prompt allowance of the claims pending in this application is earnestly solicited.

Respectfully submitted.  
**NATH & ASSOCIATES PLLC**



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